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10/687,748

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06/08/2010

EXAMINER

BLATT, ERIC D

ART UNIT

PAPER NUMBER

3734

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/687,748 | <b>Applicant(s)</b><br>NISHIKI, ABE |  |
|                              | <b>Examiner</b><br>Eric Blatt        | <b>Art Unit</b><br>3734             |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 December 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

In view of the Appeal Brief filed on March 20, 2008, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the pawl being attached to the second handle grip by a second pivot pin must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-8 and 12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 3 recites that the curved rack is attached to the first handle grip by a first pivot pin and the pawl is attached to the second handle grip by a second pivot pin. This second pivot pin is not shown in the drawings, and is mentioned only once in the specification in Paragraph 29 of the associated pre-grant publication 2004/0098003. This passage reads, "Ratchet mechanism 6 is equipped with a pawl 7, pivotably held by a second pivot pin on one handle grip 2R, and a rack 8, attached to the other handle grip." One skilled in the art would not understand from this disclosure how to use the second pivot pin. The specification explains that the rack and pawl are selectively engaged and disengaged with one another by rotating the rack about the first pivot pin, but the specification fails to address any application wherein the pawl is rotated about its pivot pin. Furthermore, pivotally mounting the pawl would seemingly allow the pawl to freely pivot out of engagement with the rack, thereby preventing proper function of the ratchet as disclosed. No means for preventing the pawl from freely pivoting out of engagement with the rack is disclosed. One skilled in the art would not understand from this disclosure how to properly operate this a ratchet wherein both the rack and pawl are pivotally mounted and no means for preventing the pawl from pivoting out of engagement with the rack is disclosed.

Claims 4-8 and 12 depend from claim 3.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Chang (US 6,663,562).

Chang discloses a phimosis curer (Figure 1) comprising first and second handle grips 20, first and second jaws 12, 18, and first and second blades 78 wherein the handle grips, jaws and blades are joined to one another as claimed. The blades extend upward from the jaws so as to be insertable into a foreskin opening. Moving the handle grips toward one-another causes the jaws to move away from each other. A ratchet means 30 pivots between the handle grips adjacent the ends of the handle grips that are attached to their respective jaws and is designed to selectively prevent the handle grips from moving away from each other. The blades comprise hook means (enlarged paddles shown in Figure 7A) wherein the hook means comprise tip sides, front sides and rear sides such that each of these sides protrude. (The hook means protrudes in 3 directions as shown in Figure 7A) The construction of these hook means is capable of preventing the blades from slipping out of a foreskin opening when the blades are separated within a foreskin opening so that the device will not damage the foreskin. There is a fulcrum pin 14 attaching the first handle grip and the second handle grip so

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that the first handle grip the first jaw may be pivoted relative to the second handle grip and the second jaw. The entirety of the device is one integral part since all of the elements work together to form an integrated device.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 5, and 12-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (US 6,663,562) in view of Ramamurti et al. (US 6,635,072).

Regarding claims 3 and 5, Chang discloses the invention substantially as claimed including the curved rack having a smooth side, an irregular cog surface 36, and the pawl being attached to the second handle grip by a pivot pin. Chang fails to disclose that the rack is attached to the first handle grip by a pivot and that the rack pivots toward the pawl to selectively engage the pawl with the irregular cogs and away from the pawl to remove the rack from contact with the pawl. Ramamurti discloses a similar device and teaches that the rack may be pivotally mounted such that it pivots to engage a pawl with cogs on the rack and away from the pawl to remove the rack from contact with the pawl. It would have been obvious to one of ordinary skill in the art to modify the apparatus of Chang by pivotally mounting the rack on the first handle grip via a pivot pin since Ramamurti teaches that this was a known construction and its use

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would not have produced unexpected results. With regard to claim 12, Ramamurti further teaches providing a biasing spring in combination with the pivot pin attaching the rack to the first handle grip for biasing the cogs on the ratchet rack toward the pawl. (Col. 3, Lines 3-5) It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the modified device with a biasing spring in order to achieve these benefits as taught by Ramamurti.

Regarding claims 13, 14 and 16, Chang fails to disclose a spring provided with the fulcrum pin for biasing the first and second handle grips away from each other. Ramamurti discloses a related device and teaches that a spring 28 may be provided in combination with a fulcrum pin 18 to bias handle grips away from one another. (Col. 5, Lines 9-11) It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Chang with a spring element as taught by Ramamurti for purposes such as keeping the blades together until a surgeon is ready to spread the target tissue. As previously discussed, the entirety of the device is one integral part since all of the elements work together to form an integrated device. Provided with this biasing spring, the device would comprise one integral shaped spring element. The handle grips are united together via pin 14, and the first and second jaws are considered to criss-cross each other since they briefly cross over one another near pin 14.

Regarding claim 15, the ratchet means comprises a rack 32 attached to the second handle grip and having a first side edge and a second side edge wherein cogs 36 are formed along the first side edge. The ratchet means is engaged by selectively



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placing a portion of the first handle grip (pawl 34) into one of the cogs. Chang thus discloses all elements of claim 15 except for the rack being flat. The Chang ratchet rack is curved and is fixed to the second handle grip while the pawl pivots to engage the rack. Ramamurti discloses that the rack may instead be flat and may be pivotally mounted to the second handle grip to engage a static pawl. (Figure 1) It would have been obvious to one of ordinary skill in the art to modify the apparatus of Chang by instead using a flat rack construction since Ramamurti teaches that this was a known alternative and its use would not have produced unexpected results.

Claims 4 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (US 6,663,562) in view of Ramamurti et al. (US 6,635,072) as applied to claim 3 above, and further in view of Seber et al. (U.S. Patent No. 6,748,829).

Chang and Ramamurti teach the invention substantially as claimed including resilient means to bias the curved rack toward the pawl (see ref. 28 of Ramamurti). Chang and Ramamurti fail to disclose the curved rack having a slot that is wide enough to accommodate a pawl in an engaged position and a disengaged position. Seber teaches a curved rack with a slot (see Fig. 2A and 3A) for the purpose of allowing the pawl to move within the curved rack. It would have been obvious to one having ordinary skill in the art to further modify the apparatus of Chang by providing a slot in the curved rack that accommodates the pawl as disclosed by Seber et al. in order to allow the pawl of one handle grip to remain connected to the slot of the other handle grip so that they do not become separated during use.

Chang also fails to disclose the curved rack having a guide groove, the second handle grip having a spring loaded projection, a stop positioned on the second handle grip, the spring-loaded projection extending into the guide groove and the guide groove terminating in a decreasing depth taper. Seber teaches a curved rack with a guide groove 40, a spring-loaded projection 84, a stop positioned on the second handle grip (ends of ref. 40 act as a stop) for the purpose of controlling the pivotal movement of the curved rack. It would have been obvious to one having ordinary skill in the art at the time of the invention to have provided the device of Chang with a spring-loaded projection that is inserted into a guide groove, as taught by Seber, in order to allow for engagement and disengagement of the pawl with the cogs of the curved rack. It is well-known in the art to have a decreasing depth taper on a slot in order to allow for an element that is inserted into the slot to easily move into and out of the slot.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (US 6,663,562) in view of Brennan et al. (US 6,450,975)

Chang discloses all elements of claims 9 and 10 except for the enlarged hook means being in the general shape of a ball (claim 9) and being coated with an inert material not harmful to the human body (claim 10). The device of Chang may be used to exert force against sensitive body tissue. Bennan teaches that a device which contacts body tissue may be provided with a smooth ball tip 16 in order to minimize trauma to the contacted tissue. (Figure 1, Abstract) It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the blades of the change

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device by providing smooth ball tips at their respective ends in order to minimize tissue trauma as taught by Brennan. Brennan additionally teaches that a tissue contacting device may be provided with a low friction coating comprising a polymer such as Teflon. (Col. 8, Lines 27-40) It would have been obvious to provide the smooth ball tips with a Teflon coating in order to further reduce the risk of tissue damage.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric Blatt whose telephone number is (571)272-9735. The examiner can normally be reached on Monday-Friday, 9:00 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/E. B./

Examiner, Art Unit 3734

/TODD E. MANAHAN/

Supervisory Patent Examiner, Art Unit 3734